

APPLICANTS: Farmer
U.S.S.N.: 09/647,695

30. The method of claim I wherein said patient is at risk for atherosclerosis, arterial sclerosis, myocardial infarction, heart attack, diabetes, coronary heart disease, angina pectoris or unstable angina.

BS 77. (amended) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an [effectic] effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is Sporolactobacillus P44.

REMARKS

Claims 1, 4, 8-30 and 77 are pending. Claims 2-3 were canceled.

No new matter has been added by this amendment.

35 U.S.C. § 112

Claims 2-3 were rejected for indefiniteness. In view of the cancellation of these claims, this rejection can now be withdrawn.

35 U.S.C. 103

Claims 1-4, 8-30 and 77 were rejected for obviousness over Paul in view of Fukushima, Bova, and Mandeville. Claims 2-3 were canceled. With respect to the other claims, this rejection is traversed.

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On page 10, lines 3-11, of Paper No. 12, the Examiner states:

Applicant urges that the references do not teach *Bacillus coagulans* for reducing serum cholesterol and that there is no suggestion or motivation to use the particular claimed species of *Bacillus* in the methods of Paul.

However, these arguments fail to persuade, because as clearly demonstrated by the cited references, it was well known in the art that lactic acid bacteria were well known to reduce serum cholesterol levels and increase serum HDL. Although the references do not name the specifically claimed species, it would have been obvious to one of ordinary skill in the art to use any known lactic acid bacteria because they were well known to have the beneficial effects, as claimed.

Claim 1 specifically requires a *Bacillus coagulans* bacterium. Claim 77 requires *Sporolactobacillus* P44. None of the cited references describe or suggest the specific species required by independent claim 1 or 7. The remaining pending claims depend from claim 1.

As is discussed above, claim 1 was amended to require a *Bacillus coagulans* bacterium, and Paul fails to describe such a bacterium. In fact, Paul is limited to *Lactobacilli* sp. and *Bifidobacteria* sp. Thus, the amended claims are not obvious over this reference.

Claims 1-4 were rejected over Paul in view of Fukushima. Claim 2 has been canceled, and claim 1 has been amended to require a *Bacillus coagulans* bacterium. Paul is limited to a description of *Lactobacilli* sp. and *Bifidobacteria* sp. The Fukushima et al. abstract describes a composition containing a mixture of *Bacillus*, *Lactobacillus*, *Streptococcus*, *Saccharomyces* and *Candida* species, but fails to describe *Bacillus coagulans*. Because there is no suggestion to administer the particular bacterium required by the amended claims, the claims are non-obvious over this combination of references.

Claims 1 and 19-25 were rejected for anticipation by Paul in view of Bova et al. Bova is cited for a description of compounds and methods for reducing cholesterol. Neither Paul nor

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Bova describe or suggest administering a composition containing *Bacillus coagulans*, as required by the amended claims. Therefore, this rejection should be withdrawn.

Claims 1 and 26-28 were rejected for obviousness over Paul in view of Mandeville et al.

On page 14, lines 4-7, of Paper No. 9, the Examiner states:

one of ordinary skill in the art would have been motivated by Mandeville, III et al. to include a cholic acid complexation (sequestering) agent in the method of Paul with a reasonable expectation of success for reducing serum cholesterol because of the cholesterol/lipid reducing effects as demonstrated by Mandeville, III et al.

This rejection is also met by the present amendment. Paul does not describe or suggest *Bacillus coagulans* administered alone or in combination with another composition for reducing cholesterol. Mandeville et al. does not remedy this deficiency. The combination of Paul and Mandeville fail to disclose or suggest a critical element of the amended claims, i.e., *Bacillus coagulans*.

Applicants submit that the present amendment distinguishes the invention from the cited art and therefore request withdrawal of the rejections under § 103.

35 U.S.C. § 112

Claims 12 and 24-28 were rejected for indefiniteness.

The claims were amended for clarity and to correct typographical errors. The rejection under §112 can now be withdrawn.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the

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telephone number provided below.

A petition for a two-month extension of time and a check in the amount of \$200.00 is enclosed to cover the petition fee for a two-month extension of time pursuant to 37 C.F.R.

§ 1.17(a)(2). The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19374-502 NATL.

Respectfully submitted,



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Appendix: Marked up version of claims.

In the claims:

Claims 1, 2, 3, 12, 24, 27 and 77 have been amended as follows:

1. (twice amended) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an [effectic] effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is *Bacillus coagulans*.

2. (Cancelled).

3. (Cancelled).

12. (twice amended) The method of claim 11 wherein said administering comprises introducing into the digestive tract [ofrom] from 5×10^8 to 5×10^9 viable bacteria per day.

24. (twice amended) The method of claim 19, wherein said fiber product is selected from the group consisting of [gembibrozil] gemfibrozil, [fenobibrate] fenobibrate, psyllium, bran, glucomannan and Jerusalem artichoke flour.

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27. (twice amended) The method of claim 26 wherein [siad] said complexation agent is a salt of a metal selected from the group consisting of calcium, chromium, copper, iodine, iron, magnesium, manganese, potassium sodium, and zinc

77. (amended) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an [effectic] effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is

Sporolactobacillus P44.